

BEFORE THE TAX COMMISSION OF THE STATE OF IDAHO

In the Matter of the Petition for)	
Redetermination of,)	
)	DOCKET NO. 17933
[REDACTED])	
)	DECISION
Petitioner.)	
_____)	

On February 26, 2004, the [Redacted] (taxpayer) filed a refund claim asking for a refund of sales tax paid in error in the amount of \$4,961.47. The sales tax was paid on purchases of various drugs and medical devices made during the period of January 2001 through December 2003.

The sales tax audit staff reviewed the refund claim and allowed a refund of \$1,931.17 with interest of \$78.83 for a total of \$2,010.00

The taxpayer protested the partial refund denial on March 4, 2004. The taxpayer requested an informal hearing, which was held on May 4, 2004.

One of the taxpayer's vendors had charged tax incorrectly on several items, including prescription drugs. The taxpayer claimed a refund, pursuant to sales tax administrative rule 117 (IDAPA 35.01.02.117). A member of the Tax Commission's sales tax audit staff reviewed the refund claim. The auditor allowed the refund on purchases of prescription drugs. He denied the refund for sales tax paid on purchases of intrauterine devices (IUDs). This is the tax at issue in this case.

IUDs are used as a means of contraception. The taxpayer has explained that it purchased two different types of IUDs. One type, known as the Mirena IUD manufactured by Berlex, Inc. and distributed by Theracom, Inc., contains a reservoir of the hormone levonorgestrel. The hormone is released gradually and the IUD has to be replaced after one year. The other type, the Paragard T

380A manufactured by Ortho-McNeil, is made of plastic and copper and does not contain hormones or other substances that are absorbed by the body. The taxpayer stated that the copper prevented sperm cells from fertilizing egg cells. The Paragard T package insert, however, states; “How the ParaGard T 380A prevents pregnancy is not understood at the present time.” Only a doctor can insert an IUD of either type.

Idaho Code § 63-3622N provides an exemption for certain sales of prescription drugs, prosthetic devices, and durable medical equipment when sold or administered to an individual by a licensed medical practitioner. That statute states:

63-3622N. PRESCRIPTIONS. -- (a) There are exempted from the taxes imposed by this chapter the following when administered or distributed by a practitioner licensed by the state under title 54, Idaho Code, to administer or distribute such items or when purchased by or on behalf of an individual for use by such individual under a prescription or work order of a practitioner licensed by the state under title 54, Idaho Code, to prescribe such items:

- (1) Drugs, hypodermic syringes, insulin, insulin syringes, artificial eyes, hearing aids, and hearing aid parts and accessories;
- (2) Drugs and supplies used in hemodialysis and peritoneal dialysis;
- (3) Braces and other orthopedic appliances;
- (4) Dental prostheses and other orthodontic appliances, but not including fillings;
- (5) Catheters, urinary accessories, colostomy supplies, and other prosthetic devices which shall include, but is not limited to, enteral and parenteral feeding equipment and supplies, (tubing, pumps, containers) catheter devices and supplies, but not including eyeglasses and contact lenses;
- (6) Equipment and devices or chemical reagents which are used to test or monitor blood or urine of a diabetic;
- (7) Other durable medical equipment and devices and related parts and supplies specifically designed for those products which shall include, but is not limited to: oxygen equipment, oxygen cylinders, cylinder transport devices (sheaths, carts), cylinder stands, support devices, regulators, flowmeters, tank wrench, oxygen concentrators, liquid oxygen base dispenser, liquid oxygen portable dispenser, oxygen tubing, nasal cannulas, face masks, oxygen humidifiers, oxygen fittings and accessories, respiratory therapy equipment, room humidifiers, aspirators,

aerosol compressors (stationary and portable), ultrasonic nebulizers, volume ventilators, respirators and related device supplies, percussors, vibrators, IPPB, circuits, devices and supplies, air oxygen mixers, manual resuscitators, nebulizers, tubing, emergency oxygen delivery units, patient care equipment, physical and occupational therapy items, hospital beds, trapeze bars and bar stand, bed rails, geriatric chairs, lift recliners, bedside commodes, overbed tables, patient lifts, patient lift slings, traction stands and pulleys, shower seating, shower grip bars, raised toilet seats, toilet safety frames, walking canes, quad canes and accessories, walkers, wheeled walkers, walker accessories, I.V. stands, crawlers, posture back supports for seating, posture back supports, wheelchairs, crutches, crutch pads, tips, grips, restraints, standing frame devices and accessories, hand exercise equipment and putty, specially designed hand utensils, leg weights, paraffin baths, hydrocollators, hydrotherm heating pads, communication aids for physically impaired, specialized seating, desks, work stations, foam wedges, writing and speech aids for the impaired, dressing aids, button loops and zipper aids, grooming aids, dental aids, eating and drinking aids, splints, holders, household aids for the impaired, shampoo trays, reaching aids, foam seating pads, decubitus seating pads, bed pads, fitted stroller, alternating pressure pads and pumps, stethoscope, sphygmomanometers, otoscopes, sitting and sleeping cushions, patient transport devices, boards, stairglides, lifts in home, transcutaneous nerve stimulators, muscle stimulators, bone fracture therapy devices.

(b) The term "practitioner" means a physician, surgeon, podiatrist, chiropractor, dentist, optometrist, psychologist, ophthalmologist, nurse practitioner, denturist, orthodontist, audiologist, or hearing aid dealer or fitter.

(c) The term "drug" means a drug which is:

(1) Defined in section 54-1705, Idaho Code, and

(2) Either:

(i) listed in a drug compendia which the state board of pharmacy requires to be maintained by Idaho licensed pharmacies, or

(ii) the use of which requires a prescription under state or federal law. The term shall not include articles intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in animals other than man.

(d) The term "durable medical equipment" means equipment which:

(1) Can withstand repeated use;

(2) Is primarily and customarily used to serve a medical purpose;

(3) Generally is not useful to a person in the absence of illness or injury; and

(4) Is appropriate for use in the home.

(e) The term "prosthetic device" means a device which replaces a missing part or function of the human body and shall include any supplies physically connected to such devices. (Emphasis added.)

Idaho Code § 54-1705(7), in turn, defines drug as:

(7) "Drug" means:

(a) Articles recognized as drugs in the official United States Pharmacopoeia, official National Formulary, official Homeopathic Pharmacopoeia, other drug compendia or any supplement to any of them;

(b) Articles intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man or other animal;

(c) Articles, other than food, intended to affect the structure or any function of the body of man or other animals; and

(d) Articles intended for use as a component of any articles specified in paragraph (a), (b) or (c) of this subsection.

In addition, Idaho Code § 54-1705(4) provides the following definition for "device":

(4) "Device" means an instrument, apparatus, implement, machine, contrivance, implant, invitro reagent or other similar related article including any component part or accessory which is:

(a) Recognized in the official United States Pharmacopoeia or official National Formulary, other drug compendia or any supplement to them;

(b) Intended for use in the diagnosis of disease or other conditions, or the cure, mitigation, treatment or prevention of disease in man or other animal;

(c) Intended to effect the structure or any function of the body of man or other animal, and which does not achieve any of its principal intended purposes through chemical action within or on the body of man or other animal, and which is not dependent upon being metabolized for the achievement of any of its principal intended purposes.

These two definitions are obviously similar. The primary distinction between a "drug" and a "device" is that a device does not react chemically with the body and is not metabolized.

At first glance it would appear that neither definition applies to IUDs. IUDs are used for contraception and not for use in the diagnosis, cure, mitigation, treatment or prevention of disease in

man. The definition, however, is substantially the same as the definition found in the federal Food, Drug, and Cosmetic Act, 21 USCA § 321(g)(1), as it existed prior to the enactment of the Dietary Supplement Health and Education Act of 1994. The United States Supreme Court, however, has ruled that the definition is intended to be disjunctive. In other words, if a substance meets any of the criteria in the definition, it is a drug. *United States v. Generix Drug Corp.*, 460 U.S. 453, 103 S.Ct. 1298, (1983). There are also cases that have held that, regardless of the actual physical effect of a product, it will be deemed a drug if the labeling, including separate promotional claims, attributes characteristics to the product that would bring it within the Act's definition. *Kordel v. United States*, 1948, 335 U.S. 345, 69 S.Ct. 100; *United States v. Hohensee*, 3d Cir. 1957, 243 F.2d 367, cert. den. 353 U.S. 976, 77 S.Ct. 1058. See *United States v. Article of Drug*, 3d Cir. 1966, 362 F.2d 923. Courts have held that, depending on how the products are marketed, cosmetics (*United States v. Article Consisting of 36 Boxes*, 415 F. 2d 369 (1969)), and honey (*United States v. 250 Jars, etc., of Fancy Pure Honey*, 218 F.Supp. 208, affd 344 F.2d 288 (1963)) are drugs.

The definition of “device” in Idaho Code § 54-1705(4) is also taken from the Food, Drug, and Cosmetic Act. See 21 USCA § 321(h). Congress enacted the Medical Device Amendments to the FDCA in 1976, 21 USC § 360c. That act created three classes of devices, each with a different standard for premarket approval. At the current time, the Food and Drug Administration, by regulation, classifies some IUDs as devices rather than drugs. See 21 CFR 884.5360. The definition of IUD in this regulation, however, does not include IUDs that function by drug activity.

From the decisions cited above, it is clear that congress intended to define the term “drug” broadly to give the FDA the widest scope possible in its regulatory authority. For the same reason, the Idaho legislature adopted a similar definition for the Idaho Pharmacy Act. To a certain extent, then, the Pharmacy Act and the Sales Tax Act are at cross-purposes. The definition of “drug” in the

Sales Tax Act is part of an exemption statute. Tax exemptions are to be construed strictly against the taxpayer. In the recent decision of the *Idaho State Tax Commission v. Stang*, The Idaho Supreme Court stated:

If there is any ambiguity in the law concerning tax deductions, the law is to be construed strongly against the taxpayer. [*Potlatch Corp. v. Idaho State Tax Comm'n*, 128 Idaho 387, 913 P.2d 1157 (1996)] *.Id.* This Court has no authority to rewrite the tax code. *Bogner v. State Dep't of Revenue and Taxation*, 107 Idaho 854, 693 P.2d 1056 (1984). Any exemption from taxation must be created or conferred in clear and plain language and cannot be made out by inference or implication. *Herndon v. West*, 87 Idaho 335, 393 P.2d 35 (1964). This Court does not have the authority to create deductions, exemptions, or tax credits. If the provisions of the tax code are socially or economically unsound, the power to correct it is legislative, not judicial. *Id. Idaho State Tax Commission v. Stang*, 135 Idaho 800, 25 P.3d 113 (2001).

The Tax Commission, therefore, is required to view exemptions narrowly. For this reason, and also because the FDA classifies the copper IUDs as a device and not a drug, the Commission finds that the Paragard T is not a drug. Unless it otherwise qualifies for exemption, sales of such IUDs are taxable. On the other hand, the Mirena IUDs are used to administer levonorgestrel, a substance that does meet the definition of “drug.” For this reason, sales of Mirena IUDs qualify for the prescription drug exemption when sold to an individual under a doctor’s prescription or when sold to a health care provider.

Idaho Code § 63-3622N also exempts sales of prosthetic devices and durable medical equipment. The definition of “prosthetic device” requires that the device replace a missing part or function of the human body. Since IUDs are intended to prevent a normal function of the body--pregnancy--they do not meet the requirements of the statutory decision.

Finally, the exemption also applies to sales of durable medical equipment. The definition in

Idaho Code § 63-3622N is taken from the Medicare regulations promulgated by the Department of Health and Human Services. See 42 CFR § 414.202. The list of examples in Sec. 63-3622N is limited to items that improve the quality of life for people with disabilities. The list does not include contraceptive devices. Unlike the definition of “drug,” an item must meet all the elements of the definition to qualify. Idaho Code § 63-3622N(d)(3) states that durable medical equipment is generally not useful to a person in the absence of illness or injury. Since IUDs are not used to alleviate the effects of an illness or injury, they cannot be included in the definition of “durable medical equipment.”

In summary, sales of the Mirena IUD will qualify for the exemption as a prescription drug sold or administered to an individual by a licensed health care practitioner. Sales of the copper Paragard IUDs do not qualify for the exemption. Sales of these IUDs are taxable when sold to an individual or health care provider unless another exemption applies. The Notice of Deficiency Determination Refund Denial will be modified to reflect this ruling.

Finally, the taxpayer has pointed out that the original refund was incorrect. The original refund should have been \$2,236 instead of \$1,931. The additional \$305 will be added to the refund of allowed tax paid on purchases of the Mirena IUDs.

WHEREFORE, the Notice of Deficiency Determination Refund Denial dated February 26, 2004, is hereby MODIFIED, APPROVED, AFFIRMED and MADE FINAL.

IT IS ORDERED and THIS DOES ORDER that the taxpayer receive a refund as follows:

<u>TAX</u>	<u>INTEREST</u>	<u>TOTAL REFUND</u>
\$1,868	\$135	\$2,003

An explanation of [Redacted]right to appeal this decision is enclosed.

DATED this _____ day of _____, 2004.

IDAHO STATE TAX COMMISSION

COMMISSIONER

CERTIFICATE OF SERVICE

I hereby certify that on this ____ day of _____, 2004, a copy of the within and foregoing DECISION was served by sending the same by United States mail, postage prepaid, in an envelope addressed to:

[REDACTED]

Receipt No.
